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MAYER & WILLIAMS PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER	
HUGHES, ALICIA R	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,054	RICHARD ET AL.	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) *15 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-14 and 16-18 are pending and the subject of this Office Action.

Restriction Requirement

Applicant's election of species, with traverse, in the reply filed on 29 March 2007 is acknowledged. The traversal is on the ground(s) that Applicants believe that "a search and examination of the entire application can be made without serious burden." This argument is not deemed persuasive because the claims, as presented support more than one distinct invention and a search for prior art directed to one invention would not necessarily yield results for the other, especially given their differing classifications and divergent subject matter, as noted in the first requirement for restriction forwarded from this Office.

Therefore, Claims 15 and 19-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. The requirement is still deemed proper and is therefore made FINAL.

Claim Interpretation

For the purpose of examination herein, the pending claims are given their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view

of the specification" without importing limitations from the specification into the claims unnecessarily). *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969).

Claim Rejections - 35 U.S.C. §112.2

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phraseology "substantially increase the cumulative release" is not defined by claim 1, and the specification does not provide a standard for ascertaining the requisite degree thereof. As a result, one of ordinary skill in the art would not be reasonably apprized of the scope of the invention and it is therefore indefinite.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 16-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent Application No. 10/894,400. Although the conflicting claims are not identical, they are not patentably distinct from each other, because they contain identical subject matter, particularly an insertable or implantable medical device comprising a release region containing a copolymer that is a triblock copolymer and at least one therapeutic agent. Specifically, with regard to the polymeric regions, it is appreciated that the limitations for, polydiene blocks, poly(olefin-co-diene) blocks, poly

(vinyl aromatic) blocks, and poly (alkyl methacrylate) blocks, and poly (vinyl pyridine) blocks, for example, are functional equivalents to the triblock copolymers of the present invention. See, U.S. Patent Publication No. 2002/0099438, paras, 35-36. This is a provisional obviousness-type double patenting rejection, since the claims have not, in fact, been patented.

Claims 1-14 and 16-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-23 of U.S. Patent Application No. 10/632,008. Although the conflicting claims are not identical, they are not patentably distinct from each other, because they contain identical subject matter, particularly an insertable or implantable medical device comprising a release region containing a copolymer that is a triblock copolymer and at least one therapeutic agent. Specifically, with regard to the polymeric regions, it is appreciated that the limitations for, poly (alkyl methacrylate) blocks, and poly (vinyl pyridine) blocks, and silicone blocks, for example, are functional equivalents to the triblock copolymers of the present invention. See, U.S. Patent Publication No. 2002/0099438, para. 36. This is a provisional obviousness-type double patenting rejection, since the claims have not, in fact, been patented.

Claims 1-14 and 16-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent Application No. 10/409,358. Although the conflicting claims are not identical, they are not patentably distinct from each other, because they contain identical subject matter, particularly an insertable or implantable medical device comprising a polymeric release region treated with a radiation dose of at least 100,000 rads and comprising at least one therapeutic agent. Specifically, with regard to the polymeric regions, it is appreciated that the limitations for, polydiene blocks, poly(olefin-

co-diene) blocks, poly (vinyl aromatic) blocks, and poly (alkyl methacrylate) blocks, and poly (vinyl pyridine) blocks, for example, are functional equivalents to the triblock copolymers of the present invention. See, U.S. Patent Publication No. 2002/0099438, paras, 35-36. This is a provisional obviousness-type double patenting rejection, since the claims have not, in fact, been patented.

Claim Rejections – 35 U.S.C. §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4-9 are rejected under 35 U.S.C. §102(b) as being anticipated clearly by U.S. Patent No. 5,674,242 [hereinafter referred to as "Phan et al"](please refer to Phan et al in its entirety). Phan et al. teach discloses an endoprosthetic device, or stent, for the insertion at a vascular site where the stent comprises a polymer and a therapeutic compound (See Abstract; see also Col. 1, lines 16-19 and lines 33-38), which may be an antiproliferative agent (Col. 2, lines 41-46). Phan et al also teach that "[t]he polymer member has an embedded drug for release from the member when it is placed at the target site" (Col. 2, lines 2-4).

With regard to the interpretation of claim 1, particularly the clause, ""wherein said polymeric release region ...," it is important to note that as a matter of alw, the determination of whether a wherein clause is a limitation in a case depends of the specific facts of the case. In *Hoffer v. Microsoft Corp.*, 405 F. 3d 1326, 1329, 74 USPQ 2d 1481, 1483 (Fed. Cir. 2005), the

court held that "when a 'whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." *Id.* In consideration of the foregoing in the instant matter, for purposes of examination herein, "wherein said polymeric release region is treated with a radiation does that is effective to substantially increase the cumulative release of said therapeutic agent subsequent to administration to a patient" is assigned patentable weight, because it states a condition critical to patentability.

Importantly, Phan et al also teach that the polymer used is a heat-sensitive polymer and in particular, a methacrylate-containing or an acrylate-containing polymer that is prepared by mixing the monomers methyl methacrylate, polyethyleneglycol methacrylate, and butylmethacrylate in a 2:1.5:1 ratio with a crosslinker, and a thermal or UV initiator (Col. 6, lines 17-27). Phan et al also teach that the crosslinking occurs by exposure to UV light, high energy electrons, and gamma radiation (Col. 6, lines 27-33; see also Example 2 at Col. 12-13). As such, irradiation is considered an inherent property of the stent of the present invention.

In light of the foregoing, Claims 1 and 4-9 are clearly anticipated by Phan et al.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-14 and 16-18 are rejected under 35 U.S.C. 103(a) as being obvious over Phan et al in view of U.S. Patent Publication 2002/0107330 A1 [hereinafter referred to as "Pinchuk et

al"](please refer to Pinchuk et al in its entirety) and in further view of U.S. Patent Publication No. 2002/0099438 A1 [hereinafter referred to as "Furst"].

The teachings of Phan et al, *supra*, are incorporated herein by reference. Phan et al also teach, in its Figures 7 through 11, the cumulative release of its therapeutic agent of periods spanning from 0 to 140 days. An inherent feature of the release of a therapeutic agent after irradiation would be increased efficacy, thereby meeting the limitations set forth in claims 10-13. See e.g., U.S. Patent No. 6,426,339, generally, and specifically, Cols. 9, lines 50-67; Col. 10, lines 7-38; Col. 16, lines 58-64; and Col. 28, lines 1-40).

Pinchuk et al teach a release rate as a function of time for stents coated with polystyrene-polyisobutylene-polystyrene copolymer (See page 2, para. 24). Pinchuk et al also teach block copolymers with a preferred triblock structure with molecular weights in excess of 40,000 Daltons and more preferably, between 90,000 and 300,000 Daltons (See paras. 30-39 and 55 on pages 2 and 3).

On of ordinary skill in the art would be motivated to combine the teachings of Phan et al with the teachings of Pinchuk et al, because of the recognized overlapping subject matter, most notably the use of stents with therapeutic agents and as well, polymers. While Phan et al discloses the use of methacrylate-containing or an acrylate-containing polymers, Pinchuk et al explicitly disclose the use of polystyrene-polyisobutylene-polystyrene copolymer. One of ordinary skill in the art will appreciate that methacrylate-containing or an acrylate-containing polymers and polystyrene-polyisobutylene-polystyrene copolymers are functional equivalents of one another making the substitutions in the art obvious variations *See* Furst, generally and specifically, at paras. 35, 37, and 77.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to develop a stent comprising a triblock copolymer such as polystyrene-polyisobutylene-polystyrene which comprises a plurality of $-CH_2-CR_1R_2$ groups and houses a therapeutic agent for release.

Claims 2-3 are rejected under 35 U.S.C. 103(a) as being obvious over Phan et al in view of U.S. Patent Publication No. 6,537,569 [hereinafter referred to as "Cruise"](please refer to Cruise in its entirety).

The relevant teachings of Phan et al, *supra*, are incorporated herein by reference. Cruise teaches a radiation cross-linked synthetic gel and its use in various applications, such as in certain medical applications where the hydrogels are implanted on or in the body of a human or animal patient and teaches that these gels may be prepared by a process of irradiating polymers (See Abstract; see also Col. 2, limes 43-50), which may include, for example, polyvinyl alcohol (Col. 2, lines 1-3).

Cruise also teaches that the macromeric solution formed is irradiated with ionizing radiation, which causes the formation of free radicals at locations along the polymer chains and at the free radical sites, the chains may become crosslinked together. The preferred radiation dose ranges from about 10kGy (the equivalent of 10,000,000 rads) to 50kGy (the equivalent of 50,000,000 rads)(Col. 4, lines 15-30), meeting the limitations set forth in claims 2 and three of the instant invention.

One of ordinary skill in the art would be motivated to combine the teachings of Cruise with the teachings of Phan et al, due to the recognized overlapping subject matter, most notbably the administration of therapeutic agents via device implantation.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to develop a stent with a polymeric release region and therapeutic agent wherein the polymeric release region would be treated with a radiation dose in excess of 10,000,000 rads to increase the cumulative release of the therapeutic agents therein.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

08 June 2007
ARH

BRIAN-YONG S. KWON
PRIMARY EXAMINER